

## CLAIMS

What is claimed is:

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1. An apparatus for assisting a patient having diabetes mellitus in controlling blood glucose, said apparatus comprising:
- a) an input means for entering a blood glucose value  $G(t_d)$  representative of a blood glucose concentration of the patient at time  $t_d$  and for entering an insulin dose value representative of an insulin dose administered to the patient prior to time  $t_d$ ;
  - b) a memory means for storing an insulin sensitivity value representative of an insulin sensitivity of the patient and for storing information for determining an insulin action value  $F_k(t_d)$  representative of a fraction of insulin action remaining at time  $t_d$  from said insulin dose;
  - c) a processor connected to said input means and said memory means for determining said insulin action value  $F_k(t_d)$  and for determining a future blood glucose value  $G(t_j)$  representative of an expected blood glucose concentration of the patient at time  $t_j$ , wherein said processor determines said future blood glucose value  $G(t_j)$  in dependence upon said blood glucose value  $G(t_d)$ , said insulin dose value, said insulin sensitivity value, and said insulin action value  $F_k(t_d)$ ; and
  - d) a display means connected to said processor for displaying said future blood glucose value  $G(t_j)$ , thereby enabling the patient to take timely corrective action to prevent hypoglycemia or hyperglycemia.
2. The apparatus of claim 1, wherein said memory means includes means for storing maximum and minimum values

defining a target blood glucose range of the patient, said processor includes means for determining if said future blood glucose value  $G(t_j)$  lies outside of said target range and means for determining said corrective action for the patient when said future blood glucose value  $G(t_j)$  lies outside of said target range, and said display means includes means for recommending said corrective action to the patient.

3. The apparatus of claim 2, wherein said memory means further includes means for storing a target blood glucose value of the patient, said corrective action comprises an administration of a supplemental insulin dose, and said processor further comprises means for determining said supplemental insulin dose in dependence upon said insulin sensitivity value and a difference between said future blood glucose value  $G(t_j)$  and said target blood glucose value.

4. The apparatus of claim 2, wherein said memory means further includes means for storing a target blood glucose value of the patient, said corrective action comprises a consumption of a number of grams of carbohydrates, and said processor further comprises means for determining said number of grams in dependence upon a difference between said future blood glucose value  $G(t_j)$  and said target blood glucose value.

5. The apparatus of claim 1, wherein said memory means further includes means for storing a hypoglycemic value indicative of a hypoglycemic threshold of the patient, said processor includes means for determining if said future blood glucose value  $G(t_j)$  lies below

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6 said hypoglycemic value, and said apparatus further  
7 comprises audio means connected to said processor for  
8 audibly alerting the patient when said future blood  
9 glucose value  $G(t_j)$  lies below said hypoglycemic  
10 value.

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1 6. The apparatus of claim 1, wherein said input means  
2 comprises a blood glucose measuring means for  
3 measuring a blood sample of the patient and for  
4 producing said blood glucose value  $G(t_d)$  from a  
5 measurement of said blood sample.

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1 7. The apparatus of claim 1, wherein said insulin dose  
2 has an insulin type, said input means includes means  
3 for entering said insulin type, and said processor  
4 includes means for determining said insulin action  
5 value  $F_k(t_d)$  in dependence upon said insulin type.

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1 8. The apparatus of claim 7, wherein said insulin  
2 type is selected from the group consisting of  
3 regular insulin and lispro insulin.

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1 9. The apparatus of claim 1, wherein said processor  
2 includes means for determining an insulin action value  
3  $F_k(t_j)$  representative of a fraction of insulin action  
4 remaining at time  $t_j$  from said insulin dose and means  
5 for determining said future blood glucose value  $G(t_j)$   
6 in further dependence upon said insulin action value  
7  $F_k(t_j)$ .

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1 10. The apparatus of claim 1, wherein said processor  
2 includes means for determining an ultimate time point  
3 at which said insulin dose will have no insulin action  
4 remaining and means for setting time  $t_j$  equal to said  
5 ultimate time point.

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dependence upon a difference between said future blood glucose value  $G(t_j)$  and said target blood glucose value.

18. The system of claim 15, wherein said memory means further includes means for storing a hypoglycemic value indicative of a hypoglycemic threshold of the patient, said processor includes means for determining if said future blood glucose value  $G(t_j)$  lies below said hypoglycemic value, and said system further comprises audio means connected to said processor for audibly alerting the patient when said future blood glucose value  $G(t_j)$  lies below said hypoglycemic value.

19. The system of claim 15, wherein said input means comprises a blood glucose measuring means for measuring a blood sample of the patient and for producing said blood glucose value  $G(t_d)$  from a measurement of said blood sample.

20. The system of claim 15, wherein said insulin dose has an insulin type, said input means includes means for entering said insulin type, and said processor includes means for determining said insulin action value  $F_k(t_d)$  in dependence upon said insulin type.

21. The system of claim 20, wherein said insulin type is selected from the group consisting of regular insulin and lispro insulin.

22. The system of claim 15, wherein said processor includes means for determining an insulin action value  $F_k(t_j)$  representative of a fraction of insulin action remaining at time  $t_j$  from said insulin dose and means

5 for determining said future blood glucose value  $G(t_j)$   
6 in further dependence upon said insulin action value  
7  $F_k(t_j)$ .  
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1 23. The system of claim 15, wherein said processor  
2 includes means for determining an ultimate time point  
3 at which said insulin dose will have no insulin action  
4 remaining and means for setting time  $t_j$  equal to said  
5 ultimate time point.  
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1 24. The system of claim 15, wherein said processor  
2 includes means for determining a plurality of future  
3 blood glucose values representative of a corresponding  
4 plurality of expected blood glucose concentrations of  
5 the patient, and wherein said display means includes  
6 means for displaying said future blood glucose values  
7 in graphical form.  
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1 25. The system of claim 15, wherein said input means  
2 includes means for entering a plurality of blood  
3 glucose values and a plurality of insulin dose values,  
4 and said system further comprises a computing means in  
5 communication with said processor for receiving said  
6 blood glucose values and said insulin dose values and  
7 for calculating from said blood glucose values and  
8 said insulin dose values an adjusted insulin  
9 sensitivity value.  
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1 26. The system of claim 25, wherein said input means,  
2 said memory means, said processor, and said  
3 display means are included in a patient-operated  
4 apparatus, said computing means comprises a  
5 healthcare provider computer, and said apparatus  
6 includes a communication means connected to said  
7 processor for establishing a communication link

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8 between said apparatus and said healthcare  
9 provider computer.

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1 27. The system of claim 26, wherein said  
2 communication means comprises a modem means  
3 for establishing said communication link  
4 through a communication network.

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1 28. The system of claim 26, wherein said  
2 communication means comprises an input/output  
3 port for establishing said communication link  
4 through a connection cord.

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1 29. A method for assisting a patient having diabetes mellitus  
2 in controlling blood glucose, said method comprising the  
3 following steps:

- 4 a) providing the patient with an apparatus for  
5 determining a future blood glucose value  $G(t_j)$   
6 representative of an expected blood glucose  
7 concentration of the patient at time  $t_j$ , wherein said  
8 apparatus comprises a memory, an input means for  
9 entering a blood glucose value  $G(t_d)$  representative of  
10 a blood glucose concentration of the patient at time  
11  $t_d$  and for entering an insulin dose value  
12 representative of an insulin dose administered to the  
13 patient prior to time  $t_d$ , a display, and a processor  
14 connected to said memory, said input means, and said  
15 display;  
16 b) storing in said memory an insulin sensitivity value  
17 representative of an insulin sensitivity of the  
18 patient;  
19 c) storing in said memory information for determining an  
20 insulin action value  $F_k(t_d)$  representative of a  
21 fraction of insulin action remaining at time  $t_d$  from  
22 said insulin dose;



23 d) entering in said processor said insulin dose value and  
24 said blood glucose value  $G(t_d)$ ;

25 e) determining in said processor said insulin action  
26 value  $F_k(t_d)$ ;

27 f) determining in said processor said future blood  
28 glucose value  $G(t_j)$  in dependence upon said blood  
29 glucose value  $G(t_d)$ , said insulin dose value, said  
30 insulin sensitivity value, and said insulin action  
31 value  $F_k(t_d)$ ; and

32 g) displaying said future blood glucose value  $G(t_j)$  on  
33 said display, thereby enabling the patient to take  
34 timely corrective action to prevent hypoglycemia or  
35 hyperglycemia.

1        30. The method of claim 29, further comprising the step of  
2        determining in said processor an insulin action value  
3         $F_k(t_j)$  representative of a fraction of insulin action  
4        remaining at time  $t_j$  from said insulin dose, and  
5        wherein said future blood glucose value  $G(t_j)$  is  
6        determined in further dependence upon said insulin  
7        action value  $F_k(t_j)$ .

1        31. The method of claim 29, wherein the step of  
2        determining said future blood glucose value  $G(t_j)$  is  
3        preceded by the steps of determining in said processor  
4        an ultimate time point at which said insulin dose will  
5        have no insulin action remaining and setting time  $t_j$   
6        equal to said ultimate time point.

1        32. The method of claim 29, further comprising the steps  
2        of determining in said processor a plurality of future  
3        blood glucose values representative of a corresponding  
4        plurality of expected blood glucose concentrations of  
5        the patient and displaying said future blood glucose  
6        values in graphical form on said display.

33. The method of claim 29, further comprising the steps of storing in said memory maximum and minimum values defining a target blood glucose range of the patient, determining in said processor if said future blood glucose value  $G(t_j)$  lies outside of said target range, determining in said processor said corrective action for the patient when said future blood glucose value  $G(t_j)$  lies outside of said target range, and recommending said corrective action on said display.

34. The method of claim 33, wherein said corrective action comprises an administration of a supplemental insulin dose, and said method further comprises the steps of storing in said memory a target blood glucose value of the patient and determining in said processor said supplemental insulin dose in dependence upon said insulin sensitivity value and a difference between said future blood glucose value  $G(t_j)$  and said target blood glucose value.

35. The method of claim 33, wherein said corrective action comprises a consumption of a number of grams of carbohydrates, and said method further comprises the steps of storing in said memory a target blood glucose value of the patient and determining in said processor said number of grams in dependence upon a difference between said future blood glucose value  $G(t_j)$  and said target blood glucose value.

36. The method of claim 29, further comprising the steps of storing in said memory a hypoglycemic value indicative of a hypoglycemic threshold of the patient,

4 determining in said processor if said future blood  
5 glucose value  $G(t_j)$  lies below said hypoglycemic  
6 value, and audibly alerting the patient when said  
7 future blood glucose value  $G(t_j)$  lies below said  
8 hypoglycemic value.

1 37. The method of claim 29, wherein said input means  
2 comprises a blood glucose meter and the step of  
3 entering said blood glucose value  $G(t_d)$  comprises the  
4 steps of measuring a blood sample of the patient with  
5 said glucose meter and producing said blood glucose  
6 value  $G(t_d)$  from a measurement of said blood sample.

1 38. The method of claim 29, wherein said insulin dose has  
2 an insulin type, said method further comprises the  
3 step of entering said insulin type in said processor,  
4 and said insulin action value  $F_k(t_d)$  is determined in  
5 dependence upon said insulin type.

1 39. The method of claim 38, wherein said insulin type  
2 is selected from the group consisting of regular  
3 insulin and lispro insulin.

1 40. A method for assisting a patient having diabetes mellitus  
2 in controlling blood glucose, said method comprising the  
3 following steps:

4 a) providing the patient with an apparatus for  
5 determining a future blood glucose value  $G(t_j)$   
6 representative of an expected blood glucose  
7 concentration of the patient at time  $t_j$ , wherein said  
8 apparatus comprises a memory, an input means for  
9 entering a blood glucose value  $G(t_d)$  representative of  
10 a blood glucose concentration of the patient at time  
11  $t_d$  and for entering an insulin dose value  
12 representative of an insulin dose administered to the

patient prior to time  $t_d$ , a display, and a processor connected to said memory, said input means, and said display;

- b) storing in said memory an insulin sensitivity value representative of an insulin sensitivity of the patient, information for determining an insulin action value  $F_k(t_d)$  representative of a fraction of insulin action remaining at time  $t_d$  from said insulin dose, and maximum and minimum values defining a target blood glucose range of the patient;
- c) entering in said processor said insulin dose value and said blood glucose value  $G(t_d)$ ;
- d) determining in said processor said insulin action value  $F_k(t_d)$ ;
- e) determining in said processor said future blood glucose value  $G(t_j)$  in dependence upon said blood glucose value  $G(t_d)$ , said insulin dose value, said insulin sensitivity value, and said insulin action value  $F_k(t_d)$ ;
- f) determining in said processor if said future blood glucose value  $G(t_j)$  lies outside of said target range;
- g) determining in said processor a corrective action for the patient when said future blood glucose value  $G(t_j)$  lies outside of said target range; and
- h) recommending said corrective action to the patient on said display.

41. The method of claim 40, further comprising the step of determining in said processor an insulin action value  $F_k(t_j)$  representative of a fraction of insulin action remaining at time  $t_j$  from said insulin dose, and wherein said future blood glucose value  $G(t_j)$  is determined in further dependence upon said insulin action value  $F_k(t_j)$ .

42. The method of claim 40, wherein the step of determining said future blood glucose value  $G(t_j)$  is preceded by the steps of determining in said processor an ultimate time point at which said insulin dose will have no insulin action remaining and setting time  $t_j$  equal to said ultimate time point.

43. The method of claim 40, further comprising the steps of determining in said processor a plurality of future blood glucose values representative of a corresponding plurality of expected blood glucose concentrations of the patient and displaying said future blood glucose values in graphical form on said display.

44. The method of claim 40, wherein said corrective action comprises an administration of a supplemental insulin dose, and said method further comprises the steps of storing in said memory a target blood glucose value of the patient and determining in said processor said supplemental insulin dose in dependence upon said insulin sensitivity value and a difference between said future blood glucose value  $G(t_j)$  and said target blood glucose value.

45. The method of claim 40, wherein said corrective action comprises a consumption of a number of grams of carbohydrates, and said method further comprises the steps of storing in said memory a target blood glucose value of the patient and determining in said processor said number of grams in dependence upon a difference between said future blood glucose value  $G(t_j)$  and said target blood glucose value.

46. The method of claim 40, further comprising the steps of storing in said memory a hypoglycemic value

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indicative of a hypoglycemic threshold of the patient, determining in said processor if said future blood glucose value  $G(t_j)$  lies below said hypoglycemic value, and audibly alerting the patient when said future blood glucose value  $G(t_j)$  lies below said hypoglycemic value.

47. The method of claim 40, wherein said input means comprises a blood glucose meter and the step of entering said blood glucose value  $G(t_d)$  comprises the steps of measuring a blood sample of the patient with said glucose meter and producing said blood glucose value  $G(t_d)$  from a measurement of said blood sample.
48. The method of claim 40, wherein said insulin dose has an insulin type, said method further comprises the steps of entering said insulin type in said processor, and wherein said insulin action value  $F_k(t_d)$  is determined in dependence upon said insulin type.
49. The method of claim 48, wherein said insulin type is selected from the group consisting of regular insulin and lispro insulin.
50. The method of claim 40, further comprising the steps of entering in said processor a plurality of blood glucose values and a plurality of insulin dose values, determining from said blood glucose values and said insulin dose values an adjusted insulin sensitivity value, and storing said adjusted insulin sensitivity value in said memory.